IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

FRESENIUS KABI USA, LLC and FRESENIUS KABI DEUTSCHLAND GMBH Plaintiffs, v. CUSTOPHARM, INC., Defendant.	§ § § § § § § § § § §	Civil Action No. 18-665-LY

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Fresenius Kabi USA, LLC and Fresenius Kabi Deutschland GmbH (collectively, "Fresenius" or "Plaintiffs") bring this action for patent infringement against Custopharm, Inc. ("Custopharm" or "Defendant").

NATURE OF THE ACTION

1. This is an action by Fresenius against Defendant for infringement of United States Patent Nos. 8,118,802 ("the '802 patent"), 8,162,915 ("the '915 patent"), and 7,828,787 ("the '787 patent") (collectively, "the Patents-in-Suit"). This action arises out of Defendant's filing of an Abbreviated New Drug Application ("ANDA") seeking approval by the United States Food and Drug Administration ("FDA") to sell generic versions of Fresenius's ropivacaine hydrochloride injection product, Naropin®, prior to the expiration of the Patents-in-Suit.

THE PARTIES

Plaintiffs

2. Fresenius Kabi USA, LLC is a Delaware limited liability company with its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047.

3. Fresenius Kabi Deutschland GmbH is a limited liability company organized and existing under the laws of Germany with a principal place of business at Else-Kröner-Straβe 1, 61352 Bad Homburg, Germany.

Defendant

4. Upon information and belief, Custopharm, Inc. is a corporation organized and existing under the laws of Texas, with its registered office at 815 Brazos Street, Suite 500 Austin, Texas 78701.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

5. This action for patent infringement arises under 35 U.S.C. § 271.

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. Custopharm admits that this Court has subject matter jurisdiction over Plaintiffs' claims under 35 U.S.C. § 271(e)(2)(A).

Personal Jurisdiction Over Defendant

8. This Court has personal jurisdiction over Defendant because, *inter alia*, it has maintained continuous and systematic contacts with the State of Texas.

9. Custopharm is incorporated in the State of Texas and has answered and appeared in this suit.

10. Custopharm does not contest personal jurisdiction in this action.

11. Upon information and belief, Custopharm has engaged in and maintained systematic and continuous business contacts within the State of Texas and has purposefully availed itself of the benefits and protections of the laws of Texas, rendering it at home in Texas.

12. Upon information and belief, Custopharm has engaged in continuous and systematic contacts with the State of Texas and/or purposefully has availed itself of this forum by, among other things, making, marketing, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell Custopharm pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities.

13. Upon information and belief, Custopharm has committed, or aided, abetted, contributed to and/or participated in the commission of the tortious action of patent infringement that has led to foreseeable harm and injury to Fresenius, which manufactures Naropin® for sale and use throughout the United States, including the State of Texas.

14. Upon information and belief, Custopharm has applied for FDA approval to market and sell a generic version of Naropin® throughout the United States, including in Texas.

15. Custopharm sent a letter dated June 22, 2018 (the "Notice Letter") to Fresenius Kabi USA, LLC stating that it had filed ANDA No. 211907 seeking FDA approval to market a generic Naropin® product prior to the expiration of the Patents-in-Suit.

16. Upon information and belief, Custopharm will market, sell, and offer for sale its proposed generic version of Naropin® in the State of Texas following FDA approval of that product.

17. Upon information and belief, as a result of Custopharm's marketing, selling, or offering for sale of its generic version of Naropin® in the State of Texas, Fresenius will lose sales of Naropin® and be injured in the State of Texas.

18. Upon information and belief, Custopharm's systematic and continuous business contacts within Texas render it at home in Texas.

19. Upon information and belief, this Court has personal jurisdiction over Custopharm for the reasons stated herein, including, *inter alia*, Custopharm's incorporation in Texas and Custopharm's activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which render Custopharm at home in the forum.

Venue

20. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400(b).

21. Custopharm does not contest the propriety of venue in this District.

22. Upon information and belief, Custopharm has a regular and established place of business in this Judicial District and has committed and/or will commit acts of infringement in this Judicial District.

23. Custopharm has a regular and established place of business in this Judicial District at least because, upon information and belief, it: (1) is incorporated in Texas and has its registered office in this Judicial District; (2) has sought approval from the FDA to market and sell its proposed generic version of Naropin®, including in this Judicial District; (3) conducts business in this Judicial District; and (4) has engaged in regular and established business contacts with Texas by, *inter alia*, marketing, making, shipping, using, offering to sell or selling Custopharm products in this Judicial District, and deriving substantial revenue from such activities.

BACKGROUND

The Patents-in-Suit

24. The '802 patent, entitled "Connector for packaging containing medical fluids and packaging for medical fluids," was duly and lawfully issued on February 21, 2012 to inventors Torsten Brandenburger and Ismael Rahimy. The named inventors assigned the '802 patent to Fresenius Kabi Deutschland GmbH. The '802 patent is listed in the Orange Book with respect to

Naropin®. The '802 patent will expire on May 18, 2023. A true and accurate copy of the '802 patent is attached hereto as Exhibit A.

25. The '915 patent, entitled "Connector for packings containing medical liquids, and corresponding packing for medical liquids," was duly and lawfully issued on April 24, 2012 to inventors Torsten Brandenburger, Klaus Heilmann, and Bernd Knierbein. The named inventors assigned the '915 patent to Fresenius Kabi Deutschland GmbH. The '915 patent is listed in the Orange Book with respect to Naropin®. The '915 patent will expire on May 23, 2024. A true and accurate copy of the '915 patent is attached hereto as Exhibit B.

26. The '787 patent, entitled "Connector for packaging containing medical fluids and packaging for medical fluids," was duly and lawfully issued on November 9, 2010 to inventors Torsten Brandenburger and Ismael Rahimy. The named inventors assigned the '787 patent to Fresenius Kabi Deutschland GmbH. The '787 patent is listed in the Orange Book with respect to Naropin®. The '787 patent will expire on October 18, 2025. A true and accurate copy of the '787 patent is attached hereto as Exhibit C.

The Naropin® Drug Product

27. Fresenius Kabi USA, LLC currently sells, promotes, distributes, and markets Naropin® in the United States.

28. Fresenius Kabi USA, LLC holds an approved New Drug Application ("NDA") No. 20533 under Section 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a) in connection with Naropin®.

Defendant's ANDA

29. Defendant filed with the FDA an ANDA under 21 U.S.C. § 355(j) seeking approval to manufacture, use, offer for sale, sell in and import into the United States a ropivacaine hydrochloride injection product containing 2 mg ropivacaine hydrochloride per 1 mL formulation,

in 100 mL and 200 mL infusion bags that Defendant asserts is a generic copy of Naropin® ("Defendant's generic Naropin® product") prior to the expiration of the Patents-in-Suit.

30. The FDA assigned Defendant's ANDA number 211907.

31. Defendant filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the Patents-In-Suit are invalid, unenforceable and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Defendant's generic Naropin® product ("Defendant's Paragraph IV Certification"). Defendant notified Fresenius of this certification, in a letter dated June 22, 2018.

32. In the Notice Letter, Defendant offered Fresenius confidential access to portions of ANDA No. 211907 on terms and conditions set forth in an attached "Offer of Confidential Access" ("OCA"). The OCA provided by Defendant contained various terms and conditions, several of which went above and beyond protections typically afforded in a protective order.

33. On July 13, 2018, Fresenius provided Defendant with a revised draft of the OCA. A final OCA was only signed on July 24, 2018. Defendant refused to produce a complete copy of its ANDA file as part of the OCA process, which Fresenius objected to.

34. On the evening of July 26, 2018, Fresenius was provided with limited excerpts of Defendant's ANDA.

35. On July 27, 2018, Fresenius requested that Custopharm provide it with samples of the container and each of the ports proposed for use in Defendant's generic Naropin® product.

36. Fresenius did not receive samples of the container and ports proposed for use in Defendant's generic Naropin® product until Friday, August 3, 2018, one business day before 45 days from the June 22, 2018 date on the face of Custopharm's letter notifying Fresenius of Custopharm's Paragraph IV Certification.

37. Given the 45-day statutory deadline to file suit set forth in 21 U.S.C. § 355(j)(5)(B)(iii) and the limited information provided by the Defendant to date, much of it shortly before the expiration of the 45-day deadline, Fresenius turns to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to further confirm their allegations of infringement and to present to the Court evidence that Defendant's generic Naropin® product falls within the scope of one or more claims of the Patents-in-Suit.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 8,118,802

38. The allegations of paragraphs 1-34 are realleged and incorporated herein by reference.

39. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendant's generic Naropin® product would infringe one or more claims of the '802 patent.

40. Defendant has infringed the '802 patent by submitting and maintaining Defendant's ANDA before the FDA seeking approval to market Defendant's generic Naropin® product before the expiration of the '802 patent.

41. Upon information and belief, Defendant actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted, and/or directed the submission and maintenance of Defendant's ANDA to the FDA.

42. Defendant induced the infringement of the '802 patent by actively and knowingly aiding and abetting the preparation, submission, and maintenance of Defendant's ANDA with the Paragraph IV Certification and the preparation to sell Defendant's generic Naropin® product in the United States.

43. Defendant was aware of the '802 patent when engaging in these knowing and purposeful activities and was aware that filing Defendant's ANDA with the Paragraph IV Certification with respect to the '802 patent constituted an act of infringement of the '802 patent.

44. Use of Defendant's generic Naropin® product in accordance with and as directed by Defendant's proposed labeling for that product would infringe one or more claims of the '802 patent.

45. Upon information and belief, Defendant intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendant's generic Naropin® product immediately and imminently upon approval of Defendant's ANDA.

46. Upon information and belief, Defendant plans and intends to, and will, actively induce infringement of the '802 patent when Defendant's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

47. Upon information and belief, Defendant knows that Defendant's generic Naropin® product is especially made or adapted for use in infringing the '802 patent and that Defendant's generic Naropin® product is not suitable for a substantial noninfringing use. Upon information and belief, Defendant plans and intends to, and will, contribute to the infringement of the '802 patent immediately and imminently upon approval of Defendant's ANDA.

48. The foregoing actions by Defendant constitute and/or would constitute infringement of the '802 patent, active inducement of infringement of the '802 patent and/or contribution to the infringement by others of the '802 patent.

49. Upon information and belief, Defendant acted without a reasonable basis for believing that it would not be liable for infringing the '802 patent, actively inducing infringement of the '802 patent, and/or contributing to the infringement by others of the '802 patent.

50. Fresenius will be substantially and irreparably harmed by Defendant's infringing activities unless the Court enjoins those activities. Fresenius will have no adequate remedy at law if Defendant is not enjoined from the commercial manufacture, use, offer to sell, sale in, and importation into the United States of Defendant's generic Naropin® product.

51. Defendant's activities render this case an exceptional one, and Fresenius is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

COUNT II FOR INFRINGEMENT OF U.S. PATENT NO. 8,162,915

52. The allegations of paragraphs 1-48 are realleged and incorporated herein by reference.

53. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendant's generic Naropin® product would infringe one or more claims of the '915 patent.

54. Defendant has infringed the '915 patent by submitting and maintaining Defendant's ANDA before the FDA seeking approval to market Defendant's generic Naropin® product before the expiration of the '915 patent.

55. Upon information and belief, Defendant actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted, and/or directed the submission and maintenance of Defendant's ANDA to the FDA.

56. Defendant induced the infringement of the '915 patent by actively and knowingly aiding and abetting the preparation, submission, and maintenance of Defendant's ANDA with the Paragraph IV Certification and the preparation to sell Defendant's generic Naropin® product in the United States.

57. Defendant was aware of the '915 patent when engaging in these knowing and purposeful activities and was aware that filing Defendant's ANDA with the Paragraph IV Certification with respect to the '915 patent constituted an act of infringement of the '915 patent.

58. Use of Defendant's generic Naropin® product in accordance with and as directed by Defendant's proposed labeling for that product would infringe one or more claims of the '915 patent.

59. Upon information and belief, Defendant intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendant's generic Naropin® product immediately and imminently upon approval of Defendant's ANDA.

60. Upon information and belief, Defendant plans and intends to, and will, actively induce infringement of the '915 patent when Defendant's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

61. Upon information and belief, Defendant knows that Defendant's generic Naropin® product is especially made or adapted for use in infringing the '915 patent and that Defendant's generic Naropin® product is not suitable for a substantial noninfringing use. Upon information and belief, Defendant plans and intends to, and will, contribute to the infringement of the '915 patent immediately and imminently upon approval of Defendant's ANDA.

62. The foregoing actions by Defendant constitute and/or would constitute infringement of the '915 patent, active inducement of infringement of the '915 patent and/or contribution to the infringement by others of the '915 patent.

63. Upon information and belief, Defendant acted without a reasonable basis for believing that it would not be liable for infringing the '915 patent, actively inducing infringement of the '915 patent, and/or contributing to the infringement by others of the '915 patent.

64. Fresenius will be substantially and irreparably harmed by Defendant's infringing activities unless the Court enjoins those activities. Fresenius will have no adequate remedy at law if Defendant is not enjoined from the commercial manufacture, use, offer to sell, sale in, and importation into the United States of Defendant's generic Naropin® product.

65. Defendant's activities render this case an exceptional one, and Fresenius is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

COUNT III FOR INFRINGEMENT OF U.S. PATENT NO. 7,828,787

66. The allegations of paragraphs 1-62 are realleged and incorporated herein by reference.

67. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendant's generic Naropin® product would infringe one or more claims of the '787 patent.

68. Defendant has infringed the '787 patent by submitting and maintaining Defendant's ANDA before the FDA seeking approval to market Defendant's generic Naropin® product before the expiration of the '787 patent.

69. Upon information and belief, Defendant actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted, and/or directed the submission and maintenance of Defendant's ANDA to the FDA.

70. Defendant induced the infringement of the '787 patent by actively and knowingly aiding and abetting the preparation, submission, and maintenance of Defendant's ANDA with the Paragraph IV Certification and the preparation to sell Defendant's generic Naropin® product in the United States.

71. Defendant was aware of the '787 patent when engaging in these knowing and purposeful activities and was aware that filing Defendant's ANDA with the Paragraph IV Certification with respect to the '787 patent constituted an act of infringement of the '787 patent.

72. Use of Defendant's generic Naropin® product in accordance with and as directed by Defendant's proposed labeling for that product would infringe one or more claims of the '787 patent.

73. Upon information and belief, Defendant intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendant's generic Naropin® product immediately and imminently upon approval of Defendant's ANDA.

74. Upon information and belief, Defendant plans and intends to, and will, actively induce infringement of the '787 patent when Defendant's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

75. Upon information and belief, Defendant knows that Defendant's generic Naropin® product is especially made or adapted for use in infringing the '787 patent and that Defendant's generic Naropin® product is not suitable for a substantial noninfringing use. Upon information and belief, Defendant plans and intends to, and will, contribute to the infringement of the '787 patent immediately and imminently upon approval of Defendant's ANDA.

76. The foregoing actions by Defendant constitute and/or would constitute infringement of the '787 patent, active inducement of infringement of the '787 patent and/or contribution to the infringement by others of the '787 patent.

77. Upon information and belief, Defendant acted without a reasonable basis for believing that it would not be liable for infringing the '787 patent, actively inducing infringement of the '787 patent, and/or contributing to the infringement by others of the '787 patent.

78. Fresenius will be substantially and irreparably harmed by Defendant's infringing activities unless the Court enjoins those activities. Fresenius will have no adequate remedy at law if Defendant is not enjoined from the commercial manufacture, use, offer to sell, sale in, and importation into the United States of Defendant's generic Naropin® product.

79. Defendant's activities render this case an exceptional one, and Fresenius is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Fresenius respectfully requests the following relief:

a. a judgment that the '802, '915, and '787 patents are valid and enforceable;

b. a judgment that Defendant's submission of the ANDA No. 211907, was an act of infringement of one or more claims of the '802, '915, and '787 patents and that the making, using, offering to sell, selling, marketing, distributing, or importing of Defendant's generic Naropin® product prior to the expiration of the '802, '915, and '787 patents will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '802, '915, and '787 patents;

c. an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 211907 or any product the use of which infringes the '802, '915, and '787 patents, shall be a date that is not earlier than the expiration of the '802, '915, and '787 patents;

d. an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendant and all persons acting in concert with Defendant from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Defendant's generic Naropin® product, or any product the use of which infringes the '802, '915, and '787 patents, or inducing

or contributing to the infringement of the '802, '915, and '787 patents until after the expiration of the '802, '915, and '787 patents;

e. an Order pursuant to 35 U.S.C. § 283 permanently enjoining Defendant and all persons acting in concert with Defendant from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Defendant's generic Naropin® product, or any product or compound the use of which infringes the '802, '915, and '787 patents, or inducing or contributing to the infringement of the '802, '915, and '787 patents, until after the expiration of the '802, '915, and '787 patents;

f. an Order enjoining Defendant and all persons acting in concert with Defendant from seeking, obtaining, or maintaining approval of the Defendant ANDA No. 211907 before the expiration of the '802, '915, and '787 patents;

g. an award of Fresenius's damages or other monetary relief to compensate Fresenius if Defendant engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Defendant's generic Naropin® product, or any product or compound the use of which infringes the '802, '915, and '787 patents, or the inducement or contribution of the foregoing, prior to the expiration of the '802, '915, and '787 patents in accordance with 35 U.S.C. § 271(e)(4)(C);

h. a judgment that this is an exceptional case and awarding Fresenius its attorneys' fees under 35 U.S.C. § 285;

i. an award of Fresenius's reasonable costs and expenses in this action; and

j. an award of any further and additional relief to Fresenius as this Court deems just and proper.

Respectfully submitted,

By: 

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Dated: April 17, 2019

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing document was served to the attorneys of record by delivery through the Court's CM/ECF system per Local Rule CV-5(b)(1) on this the 17th day of April 2019.

/s/ *Cabrach J. Connor*
Cabrach J. Connor